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PATENT

Attorney's Docket No.: BSC-177CN  
(1002/245)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS: Rooney *et al.* CONFIRMATION NO. 5883  
SERIAL NUMBER: 09/597,179 ART UNIT: 3736  
FILING DATE: June 20, 2000 EXAMINER: Wingood, Pamela L.  
TITLE: High Performance Coil Wire

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October 4, 2002  
Date of Signature

Brenda T. Kowalczyk  
Brenda T. Kowalczyk

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# TRANSMITTAL FORM

Application Serial Number	09/597,179
Filing Date	June 20, 2000
First Named Inventor	Rooney
Group Art Unit	3736
Examiner Name	Wingood, Pamela L.
Attorney Docket No.	BSC-177CN
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PATENT  
Atty. Docket No. BSC-177CN  
(1002/245)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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**AMENDMENT AND RESPONSE**

This paper is submitted in response to the pending Office Action, Paper No. 17 ("the Office Action"), mailed from the U.S. Patent and Trademark Office on July 5, 2002. Applicants submit that no extension-of-time, or related fee, is required for this Amendment and Response to be entered and considered. However, please consider this a conditional petition for the proper extension, if one is required, and a conditional authorization to charge any related extension fees or other fees necessary for entry of this paper to Deposit Account No. 20-0531.

Please make the following amendments, without prejudice, and consider the following remarks.

**In the Claims**

Please cancel claims 41-46 and 48-56.

**REMARKS**

The undersigned attorney thanks the Examiner for her time and courtesy extended during a brief telephonic interview on September 11, 2002. During the interview the undersigned attorney pointed out that the "Grenouillet" reference, relied-upon by the Examiner for rejection of pending claims, was not previously of record in this application and the Office Action failed to provide any identifying information therefor. Accordingly, Applicants were unable to locate the reference. In response, the Examiner clarified that the "Grenouillet" is U.S. Patent No. 5,373,856 to Grenouillet.

**Discrepancies in the Office Action**

As a preliminary matter, there appears to be a number of discrepancies in the Office Action with respect to claims presently pending. First, the Office Action itself is internally inconsistent because the claims listed in the Summary as pending and rejected (claims 22-26, 28-50, and 52-56) are different from the claims addressed in the Detailed Action (claims 22-30, 32-46, 48-56). Second, neither the Summary nor the Detailed Action correctly lists the claims pending in this application after entry of the Request for Continued Examination filed by Applicants on December 21, 2001. Specifically, the Office Action Summary is silent with respect to pending claim 51 and rejects canceled claims 31 and 47. Further, the Detailed Action rejects canceled claim 27. Applicants respectfully request appropriate correction.

**Status of the Claims**

Claims 22-26, 28-30, 32-46, and 48-56 are pending in the Application. Claims 22 and 41 are the sole independent claims.

Claims 22-28, 30, 32-35, 38, 41-46, 48-51, and 54 stand rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 4,748,986 to Morrison *et al.* ("Morrison") in view of U.S. Patent No. 6,106,485 to McMahon ("McMahon") and U.S. Patent No. 5,373,856 to Grenouillet ("Grenouillet"). Claim 29 stands rejected under 35 U.S.C. § 103(a) as unpatentable over Morrison, McMahon and Grenouillet, further in view of U.S. Patent No. 5,947,940 to Beisel ("Beisel"). Claims 36 and 52 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Morrison, McMahon and Grenouillet, further in view of U.S. Patent No. 5,997,517 to Whitbourne ("Whitbourne"). Finally, claims 37, 39, 40 and 53, and 55-56 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Morrison, McMahon and Grenouillet, further in view of U.S. Patent No. 5,052,404 to Hodgson ("Hodgson").

Applicants hereby cancel claims 41-46 and 48-56 without prejudice, without any intention of abandoning the subject matter of the claims, such that claims of the same, lesser, or greater scope may be pursued in the future, and without acquiescing to or agreeing with the rejection of these claims. After entry of the present Amendment, claims 22-26, 28-30, and 32-40 are pending in the Application.

Applicants respectfully traverse the outstanding rejections and respectfully request reconsideration and withdrawal of the rejection of claims 22-26, 28-30, and 32-40 for the reasons discussed below.

**Rejections Under 35 U.S.C §103(a)**

**Morrison in Combination with McMahon, Grenouillet,  
Beisel, Whitbourne, and/or Hodgson  
Fails to Teach or Suggest the Claimed Invention**

Claims 22-26, 28, 30, 32-35, and 38 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Morrison in view of McMahon and Grenouillet. Also, dependent claim 29 stands rejected under 35 U.S.C. § 103(a) as unpatentable over Morrison, McMahon and Grenouillet, further in view of Beisel. Further, dependent claim 36 stands rejected under 35 U.S.C. § 103(a) as unpatentable over Morrison, McMahon and Grenouillet, further in view of Whitbourne. Finally, dependent claims 37, 39, and 40 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Morrison, McMahon and Grenouillet, further in view of Hodgson.

Applicants respectfully request withdrawal of these rejections because Morrison, McMahon and Grenouillet, or any other reference of record, either alone or in proper combination, fail to teach or suggest every element recited in independent claim 22, or claims 23-26, 28-30, and 32-40, which depend either directly or indirectly therefrom.

Specifically, independent claim 22 recites, in relevant part, “an elongate core composed of a nickel-titanium alloy and including a length and a distal portion; a unitary coil composed of a second material and that surrounds a substantial portion of the length of the core and extends distal of the distal portion of the core; and a tip composed of a polymeric material and extending from a distal end of the coil” (emphasis added).

all 3  
The Office Action states, on page 2, that “Morrison (986) discloses a guidewire having an elongate unitary core of stainless steel or other materials, having a length and a distal portion of a unitary coil (13, Col. 2, lns. 64-67) of stainless [steel]; however, it does not have a distal tip of a polymeric material or a core of Nitinol.” Applicants agree with the Examiner that Morrison fails to teach or suggest the “tip composed of a polymeric material and extending from a distal end of the coil” or “an elongate core composed of a nickel-titanium alloy,” recited in claim 22. Contrary to the quoted statement in the Office Action, however, Morrison also does not teach or suggest “a unitary coil ...that surrounds a substantial portion of the length of the core and extends distal of the distal portion of the core,” also recited in claim 22. Instead, Morrison discloses two coils, “an elongate coil 13 [that] extends substantially the entire length [of the elongate element 12] from the proximal to near the commencement of the tapered portion 12(b),”

See p. 6

Morrison, col. 2, lines 64-67, and “[a]nother elongate coil 16 ... which adjoins the coil 13.” Morrison, col. 3, lines 11-12. Clearly, none of Morrison’s coils is “a unitary coil ... that surrounds a substantial portion of the length of the core and extends distal of the distal portion of the core,” recited in Applicants’ claim 22 (emphasis added).

McMahon fails to remedy the deficiencies of Morrison at least because McMahon also fails to teach or suggest either “an elongate core composed of a nickel-titanium alloy” or “a unitary coil ... that surrounds a substantial portion of the length of the core and extends distal of the distal portion of the core.” In contrast to the claimed invention, McMahon generally is directed to a guidewire (10) having an elongate core member (11) with a proximal core section (12), a distal core section (13), and a helical coil on the distal extremity of the distal core section. See, McMahon, col. 3, lines 43-49 (emphasis added). McMahon fails to teach a preferred material for the elongate member (11) at all, simply stating that “conventional materials ... may be used to make the guiding members of the present invention.” McMahon, col. 4, lines 25-27.

Further, Grenouillet fails to remedy the deficiencies of Morrison at least because Grenouillet also fails to teach or suggest “a tip composed of a polymeric material and extending from a distal end of the coil” or “an elongate core composed of a nickel-titanium alloy,” recited in claim 22.

First, the Office Action failed to point out with clarity and specificity, required by MPEP 706.02(j) and 2106(VII), any teaching in Grenouillet of an elongate core being composed of a nickel-titanium alloy. Applicants find no teaching or suggestion of an elongate core composed of nickel-titanium alloy, or “Nitinol,” as one species of nickel-titanium alloy is commonly known. Rather, Grenouillet teaches that the wire (2) is made preferably of stainless steel. See, Grenouillet, col. 2, lines 63-65 (emphasis added).

Second, Grenouillet does not teach or suggest “a tip composed of a polymeric material.” Instead, Grenouillet discloses that the distal end of the sheath (4) is provided with a second solder joint (16). See, Grenouillet, col. 3, lines 18-19. Grenouillet fails to teach or suggest that a polymeric material can be used to create a solder joint at the distal end of the sheath.

Finally, Beisel, Whitbourne, and Hodgson fail to remedy the deficiencies of Morrison, McMahon and Grenouillet because neither Beisel, nor Whitbourne, and Hodgson teach or suggest an elongate core composed of a nickel-titanium alloy and including a length and a distal portion; a unitary coil composed of a second material and that surrounds a substantial portion of

the length of the core and extends distal of the distal portion of the core; or a tip composed of a polymeric material and extending from a distal end of the coil, recited by Applicants' claim 22. Given that all six of these references each fails to teach or suggest at least one common feature recited in the independent claim 22, Applicants submit that a rejection of claim 22 based on any combination of them could not be properly maintained.

Thus, Applicants respectfully submit that amended claim 22 is patentable over Morrison in view of McMahon and Grenouillet (as well as over all other references of record), at least because none of the references, alone or in proper combination, teaches or suggests every element recited in independent claim 22. Because claims 23-26, 28-30, and 32-40 depend from claim 22, and recite further limitations thereon, Applicants respectfully submit that these claims are allowable as well. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of claims 22-26, 28-30, and 32-40 based on Morrison in view of McMahon and Grenouillet, as well as Beisel, Whitbourne, or Hodgson, and other references of record.

**Morrison's Combination with McMahon and Grenouillet is Improper**

Contrary to the statement in the Office Action, any modification of Morrison with teachings of McMahon and/or Grenouillet is improper. In particular, the combination proposed in the Office Action is without basis because the Office Action fails to provide any facts or arguments to show that the nature of the problem or the knowledge of one of ordinary skill in the art would suggest the combination of Morrison with McMahon and/or Grenouillet.

The statement on page 2 of the Office Action asserting that "the use of the atraumatic polymeric tip together with a floppy guidewire would minimize the likelihood of patient trauma during insertion" may or may not have been the motivation driving the inventors in the instant case. The only potential teaching for any such motivation, however, is Applicants' own patent application. Using Applicants' own invention to supply the motivation for combining references is inappropriate. As stated in M.P.E.P. § 2143.01, "[t]he mere fact that references can be combined does not render the resultant combination obvious unless the prior art suggests the desirability of the combination." In re Mills, 916 F.2d 680, 16 U.S.P.Q. 1430 (Fed. Cir. 1990). As that section further states, "although a prior art device 'may be capable of being modified to run the way the apparatus is claimed, there must be a suggestion or motivation in the reference to do so.'" In re Mills, 916 F.2d at 682.

Morrison discloses two separate coils of different materials and does not suggest substituting them with one unitary coil. Further, Morrison discloses that a flexible elongate member is formed of a "suitable metallic material having a high torsional strength, such as stainless steel, " and that "other materials can be utilized such as certain carbon steels as well as titanium and beryllium copper." Morrison, col. 2, lines 7-9. Morrison, however, does not suggest a class of alloys known for their shape memory and superelastic properties, such as nickel-based alloys, instead of carbon steels or pure titanium. Also, Morrison does not suggest any unresolved challenges in the art with regard to using a metallic distal tip

Further, McMahon not only does not motivate, but actually teaches away from having a unitary coil that surrounds a substantial portion of the length of the core and extends distal of the distal portion of the core. Particularly, McMahon discloses that a helical coil is located only on the distal extremity of the distal core section of the elongated core member, and that an intermediate portion of the guide wire proximate to the helical coil is encased by a polymeric sheath (15) having a particular surface profile designed to reduce the area of surface contact between the guidewire and a body lumen. See McMahon, col. 2, lines 41 to col. 3, line 14 and lines 45-49. A skilled artisan would not be motivated to remove the sheath and/or extend the helical coil to surround a substantial portion of the length of the core, because that would increase the surface contact between the guidewire and a body lumen.

Also, McMahon fails to specify a preferred material for the elongate member (11) at all, simply stating that "conventional materials ... may be used to make the guiding members of the present invention." McMahon, col. 4, lines 25-27. Thus, McMahon does not mention any unresolved problems with conventional materials known in the art, for example, stainless steel, and, as such, does not motivate one of ordinary skill to use nickel-titanium alloy.

Finally, Grenouillet does not cite any unresolved problems in the art with either forming the wire 2 from stainless steel, or using a non-polymeric material to create a solder joint 16 at the distal end of the sheath 14. Therefore, a skilled artisan would not be motivated to modify Grenouillet to arrive at the invention recited in Applicants' claim 22.

Moreover, it is well settled that a reference can not be properly modified to render a claim obvious under 35 U.S.C. § 103(a) or establish a *prima facie* case of obviousness when such a modification would change the principle of operation of the reference or render it inoperable for its intended purpose. See, e.g., MPEP §2143.01. Applicants respectfully point out that, for



example, replacing Morrison's two separate coils made of different materials with a unitary coil or replacing McMahon's sheath with a coil extending the helical coil to surround a substantial portion of the length of the core would change the principle of operation of these references.

Accordingly, the combination or modification of Morrison with McMahon and Grenouillet to produce Applicants' claims is improper, fails to disclose every limitation of claims 22-26, 28-30, and 32-40, and does not establish a *prima facie* case of obviousness against these claims. Thus, the rejection of claims 22-26, 28-30, and 32-40 under 35 U.S.C. § 103(a) should not be maintained.


If the Examiner maintains the rejection of claims 22-26, 28-30, and 32-40, Applicants request that the Examiner point out with particularity where there exists a motivation in either Morrison, McMahon, or Grenouillet for combining these references, as required by MPEP § 2143.03.

#### CONCLUSION

In view of the foregoing, Applicants respectfully request reconsideration, withdrawal of all grounds of rejection and objection, and allowance of claims 22-26, 28-30, and 32-40 in due course. If, in the Examiner's opinion, a telephonic interview would expedite the favorable prosecution of the present application, the undersigned attorney would welcome the opportunity to discuss any outstanding issues, and to work with the Examiner toward placing the application in condition for allowance.

Respectfully submitted,

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